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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DAVID R PRESTON & ASSOCIATES
12625 HIGH BLUFF DRIVE
SUITE 205
SAN DIEGO, CA 92130

EXAMINER	
SHEINBERG, MONIKA B	

ART UNIT	PAPER NUMBER
1634	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,621	RAUCY, JUDY	
	Examiner	Art Unit	
	Monika B Sheinberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment C

Applicants' arguments, filed 21 October 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 21-83 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21, 36-38 and 52 are vague and indefinite due to the lack of clarity of the phrase "proteins involved in drug metabolism" as seen for example in line 4. It is unclear as to the metes and bounds of the parameters that define drug metabolism and the encoded proteins that are to some undefined extent "involved" with drug metabolism. As such, claims 22-51 and 53-83 are also indefinite due to dependency from claims 21 and 52.

Claims 21 and 52 are vague and indefinite due to the lack of clarity of the compound being referred to: in claim 21, lines 10 and 14; and in claim 52, lines 14 and 18. It is unclear if the first indicated compound that the "intracellular receptor or transcription factor is bound with, associated with or activated by" (claim 21, lines 9-10) is the same or different than that compound "that induces" (line 14). As such, claims 22-51 and 53-83 are also indefinite due to dependency from claims 21 and 52.

Claims 28 and 58 are vague and indefinite due to the lack of clarity of the term "MDR1" lines 1 and 2, respectively. The claim language does not clarify that which the abbreviation is

representative of within the claim. It is requested that the full name be written out followed by the abbreviation in parentheses to clarify use of the abbreviation alone in dependent claims.

Claim 52 is vague and indefinite due to the lack of clarity in the use of compounds and test compounds. It is confusing as to whether the compounds recited in lines 14 and 18 are the same or different than the test compound under evaluation. It is requested that consistent terminology be used for clarification of that which is intended. As such claims 53-83 are also indefinite due to dependency from claim 52.

Claim 52 is vague and indefinite due to the lack of clarity in the conflicting claim language of lines 18-24; induced expression in view of altered expression. The phrases that recite "a compound that induces" and "compound altered the expression" are confusing in that the compound is known to induce, yet the claim language states the induction is indicative of an altered expression which is inclusive of both induction and repression. It is unclear as to applicants' intent of the metes and bounds of altered in the claim language; (a) altered is representative of induced expression only; or (b) altered is representative of both induced expression and repressed expression. As such claims 53-83 are also indefinite due to dependency from claim 52.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21, 29, 31, 36, 41, 44-47, 52 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Lohray et al. (USPN 6,054,453; filed 23 JAN 1998).

This rejection is maintained from the previous action mailed 20 June 2002, with respect to the previous claims 3, 4, 9, 11, 14-17, 19 and 20 for reasons of record and newly applied to the correlating claims 21, 29, 31, 36, 41, 44-47, 52 and 53. Applicants' argue that the GAL4 is not a protein involved in drug metabolism; however due to the lack clarity of the parameters of drug metabolism as recited above, the method of testing a compound and its determined "drug binding/activation capacity" (column 38, line 24) by operably linking a promoter with a reporter gene to determine a desired sequence's encoded activity is anticipated by the reference. Applicants' also argue that an intracellular receptor is not taught by the reference however, this is not a requirement of the claim in that either an intracellular receptor OR transcription factor can be encoded. As recited in the previous action, a transcriptional factor was demonstrated by the reference. Therefore the arguments are not persuasive to overcome the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 32-35, 39, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (USPN 6,054,453) as applied to claim 21 above in view of

Luskey et al (USPN 6,262,118; claim 22), Foulkes et al (USPN 5,976,793; claims 32-34), Boeke et al (USPN 5,840,579; claim 35), Klein et al (USPN 6,255,959; claim 39) and Sherr et al (USPN 6,303,772; claims 42 and 43).

This rejection is maintained from the previous action mailed 20 June 2002, with respect to the previous claims 2, 5-8, 10, 12 and 13 for reasons of record and newly applied to the correlating claims 22, 32-35, 39, 42 and 43. As described above, Lohray et al demonstrates claim 21 as applied above due to the lack clarity of the parameters of drug metabolism as recited above, the method of testing a compound and its determined "drug binding/activation capacity" (column 38, line 24) by operably linking a promoter with a reporter gene to determine a desired sequence's encoded activity is demonstrated by Lohray et al. With regard to applicant's argument that the secondary references do not perform the following:

> "teach or suggest a cell comprising a first nucleic acid molecule comprising a promoter or enhancer operable for a nucleic acid molecule encoding a protein involved in drug metabolism operably linked to a reporter gene, and a second nucleic acid molecule encoding an intracellular receptor or a transcription factor, which when bound with, associated with or activated by a compound, con operably bind with, associate with, or activate the promorter or enhancer resulting in the expression of the reporter gene",

the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Thus the rejections are reiterated and maintained from the previous office action.

Information Disclosure Statement

The information disclosure statement filed 21 October 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The US Patent with document number 20020022599 of Synold et al was not provided; in addition, the information provided on the document appears to be incorrect. Therefore this listed reference was not considered.

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 1 P.M to 8 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 13, 2003

Monika B. Sheinberg
Art Unit 1634
MBS

Jehanne Souaya
JEHANNE SOUAYA
PATENT EXAMINER
1/13/03